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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,483	02/20/2004	Kazuyo Abe	2471/108	1765
2101 7590 07/09/2008 BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618				
EXAMINER				
BADR, HAMID R				
ART UNIT		PAPER NUMBER		
1794				
MAIL DATE		DELIVERY MODE		
07/09/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,483

Applicant(s)

ABE ET AL.

Examiner

HAMID R. BADR

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant amendment filed on 04/01/2008 is acknowledged.

Claims 1-7 are being considered on their merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blortz et al. (US 5,985,337; hereinafter R1) in view of Pommer et al. (US 5,882,718; hereinafter R2).
3. R1 discloses a process for preparing protein hydrolyzates from protein containing animal products using endopeptidases (Abstract).
4. R1 preferably uses a neutral or an alkaline protease having an endopeptidase effect. (Col. 3, lines 15-17).
5. R1 makes a hydrolysate out of pork rind which has been coarsely minced. (col. 3, lines 32-36). In the hydrolysis process, the rind is comminuted mechanically and disrupted by boiling or steaming prior to the enzymic treatment to optimize the hydrolysis yield (Col. 3, lines 40-43).
6. R1 teaches heating the hydrolysate, at the end of the hydrolysis, to inactivate the enzyme. (Col. 3, lines 48-50)

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7. R1 gives amounts of water, protease, the substrate (the rind), the hydrolysis temperature and duration of hydrolysis (in hrs) in Example 1 (Col. 4).
8. R1 is silent regarding the use of plant endopeptidases.
9. R2 discloses a method for making a protein hydrolysate using various endopeptidases including serine endopeptidases (e.g. trypsin, cucumisin), cysteine endopeptidases (e.g. papain, ficain, actinidain), aspartic endopeptidases (e.g. pepsin) and metalloendopeptidase (e.g. bacillolysin) (Col. 4, lines 7-35).
10. R2 discloses the pH range and temperature of hydrolysis stating that pH and temperature will depend on the optimum working pH and temperature characteristics of the enzyme or enzymes employed (Col. 5, lines 30-45).
11. R2 discloses a method for producing a foodstuff (such as meat based foodstuff) in which is incorporated an aqueous solution comprising unhydrolyzed and/or hydrolyzed soluble protein (Col. 8, lines 37-49).
12. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the teachings of R1 using the teachings of R2 to make hydrolyzates out of animal protein containing sources. One would have done so to benefit from underutilized animal protein sources and turn them to value added products. Absent any evidence to contrary and based on the teachings of the combined references, there would have been a reasonable expectation of success to make protein hydrolyzates.

Response to Arguments

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Applicant remarks have been fully considered. However, the arguments are not persuasive for the following reasons:

1. Applicant argues that while R1 and R2 teach producing protein hydrolyzates using bacterial or fungal enzymes, and that R1 or R2 does not disclose the use of plant materials. Applicant argues that all elements of claim 1 are not disclosed or taught by the cited references.

Attention is drawn to the following facts:

a. While the use of endopeptidase in making protein hydrolysates is disclosed by R1, it is true that R1 does not make use of plant endopeptidases. R1 also teaches that the animal protein containing material is minced (comminuted) (paragraph 5 above). This is clearly done for the purpose of exposing the protein material to the hydrolytic effects of the protease. R2 teaches that proteases suitable for use in the context of its invention include proteases of bacterial, fungal, vegetable or animal origin. Such proteases may be selected from cucumisin, papain, ficain (ficin) among other proteolytic enzymes (Col. 4, lines 7-35). Those of ordinary skill in the art are familiar with cucumisin, papain and ficain and their plant origins melons, papaya, and figs respectively. Enzymes are usually used in their pure forms because they are more efficient and more economical in that form. Using the plant material to hydrolyze proteins is obvious to those of ordinary skill in the art. Given that the protein containing material should be minced (as taught by R1; paragraph 5 above) to expose the proteins more efficiently to proteolytic enzymes, it is obvious that, for instance, fig (ficin) should come out of tissue to exert its effect. As a result a mincing or grinding or chopping or a

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cutting as presently claimed is necessary. Mixing the enzyme source and the substrate (protein containing material) and keeping the mixture under suitable conditions of temperature and pH is also obvious. The last limitation of claim 1 is a heating step to stop the activity (inactivate) of the protease. This step is also taught by R1 as outlined in paragraphs 6 above. In this perspective, all elements of claim 1 are either taught or suggested by the cited references.

It is obvious to one of ordinary skill in the art to modify the teachings of R1 and adopt the teachings of R2 to make protein hydrolyzates by mixing a comminuted protein source and a plant enzyme source and simply follow the hydrolysis parameters taught by R1.

b. The proteolytic activity of plant materials has been known for over a century. Evidence to support this position is found in the following references:

Chittenden, R. H. et al 1906. Ferments in pineapple juice. Trans Connecticut Acad. 8: 1-28.

The authors explain that "Papain is the best known instance of a proteolytic ferment in the vegetable kingdom; recent research shows that such ferments are almost universally distributed, and that in pineapple juice is very remarkable in its powers. The proteolytic action of the juice tested on flesh, fibrin, white of egg etc. takes place in an acid, alkaline or best in neutral medium and at a temperature of 40°".

Deleanu, N. T. 1916. The proteolytic enzyme of Ficus carica. Bull. Sec. Sci. Acad. Roumaine. 4: 345-354.

The authors explain that " It is shown that the proteolytic enzyme from the latex of *Ficus carica* is identical with that from *Carica papaya*"

2. Applicant also argues that claim 5 of the instant application recites a hydrolyzing composition having between 80-95.5% (w) of animal protein, a limitation that is neither taught nor suggested in either R1 or R2.

R1 and R2 give examples in which the amount of protein, suspending medium (water), amount of protease, pH and temperature of hydrolysis discussed. An optimization of the process parameters will provide the best conditions regarding the type of enzyme and substrate used. Since the structure of the final product regarding type of peptides and amount of amino acids liberated will be a function of process parameters, designing a final product of certain quality will necessitate an optimization.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chittenden, R. H. et al 1906. Ferments in pineapple juice. Trans Connecticut Acad. 8: 1-28.

Deleanu, N. T. 1916. The peptolytic enzyme of *Ficus carica*. Bull. Sec. Sci. Acad. Roumaine. 4: 345-354.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794